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EXAMINER	
MILLER, MARINA I	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,594	FRUDAKIS ET AL.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *21 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9,12,15-22,24,29-32,37-45,47-59,61,72 and 76* is/are pending in the application.

4a) Of the above claim(s) *6,12,15,16,21,22,37,59,61,72 and 76* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-9,24,29-32,38-45 and 47-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election with traverse of Group I (claims 1, 3-9, 12, 15-16, 21-22, 24, 29-32, 37-45, and 47-58 directed to a method for inferring a trait of an individual) in the reply filed 11/21/2005 is acknowledged. Applicants also elected SEQ ID NO:70 for Species A and a trait of biological ancestry (BGA) for Species B recited in claim 3.

The traversal is on the ground(s) that the subject matter of Groups I, II, and III is sufficiently related and a search and examination of the entire application would not place a serious burden on the examiner. This is not found persuasive because the inventions of Groups I-III are distinct. The method of Group I and the kit of Group II are related, as set forth in the Restriction/Election requirement, but the kit can be used with a different method. The method of Group I and the article of Group II are also related, but the article may be used with a different method. MPEP 806.05(h). The examiner must search non-patent literature and foreign patents as well as U.S. patents and publications. Contrary to applicants' assertion, the search required for each group is not coextensive with that required for any other group.

Applicants also traverse the species election, *i.e.*, election of a single SEQ ID NO:70 and a single trait. The traverse is on the ground that individual markers are from a single gene, and therefore are related and should be examined together. Further, applicants state that 10 sequences may be examined in one application, and therefore all of the markers from a total of 10 different genes should be examined. Due to the increasingly large size of the sequence databases which must be searched for any single sequence, the current policy of the office is to search one sequence per application. In addition, different sequences derived from one gene do require different searches. Also, it is not clear from the disclosure that a panel of AIMs originated from

one gene does consist of sequences that compose a polynucleotide encoding a particular protein (*e.g.*, some sequences may be originated from a regulatory portion of a gene or from introns which do not encode any protein). With respect to the election of a trait, applicants assert that all traits are related to each other and search of one trait would necessarily include search of the art relevant to the other trait. The examiner maintains that a search, for example, for alcoholism or a pigmentation trait does not necessarily coincide with the search for a biogeographical ancestry or a drug resistance

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 10-11, 13-14, 17-20, 23, 25-28, 33-36, 46, 60, 62-71, 73-75, and 77-82 are cancelled.

Claims 6, 12, 15-16, 21-22, 37, 59, 61, 72, and 76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention and species, there being no allowable generic or linking claim.

Claims 1, 3-5, 7-9, 24, 29-32, 38-45, and 47-58 are currently under examination.

An action on the merits of claims 1, 3-5, 7-9, 24, 29-32, 38-45, and 47-58, as they read on the elected species, follows.

Information Disclosure Statement

Information Disclosure Statements (IDS) filed 5/20/2004 has been considered in full.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date: U.S. applications 10/156,995, filed 5/28/200 and 10/188,359, filed 7/01/2002

and PCT/US02/38345, filed 11/26/2002, for claims 1, 3-5, 7-9, 24, 29-32, 38-45, and 47-59. The instant claims are drawn to a method for inferring a trait of an individual comprising steps of contacting a sample with oligos, wherein oligos can detect SNPs of a panel of ancestry markers, and identifying a population structure that correlates with the AIMs and the trait. A method of inferring a trait wherein ancestry informative markers are used for identifying a trait are not disclosed in applications 10/156,995; 10/188,359; and PCT/US02/38345. The priority applications disclose a method for inferring a response to statin and a method for detecting polymorphism associated with pigmentation.

If applicants desire benefit of these applications, applicant is invited to point to specific support by page and line number for each limitation of instant claims in the provisional applications mentioned above. The earliest priority for claims 1, 3-5, 7-9, 24, 29-32, 38-45, and 7-59 is granted to the filing date of provisional application 60/404,357, filed 08/19/2002.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as on p. 44 and 85. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Abstract

The abstract is objected to because it does not properly describe the claimed invention, which is directed to a process. Applicant is required to submit a new abstract reflecting what is the essence of the claimed invention and set forth a process of the invention.

Claim Rejections - 35 USC § 112

Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentations is "undue." These factors include, but are not limited to:

a) The breadth of the claims;
b) The nature of the invention;
c) The state of the prior art;
d) The level of one of ordinary skill;
e) The level of predictability in the art;
f) The amount of direction provided by the inventor;
g) The existing of working examples; and
h) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. 858 F.2d at 740. While all of these factors are considered, sufficient amount for a prima facie case are discussed below.

Claim1, 3-5, 7-9, 24, 29-32, 38-45, and 47-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method wherein a SNP is detected by hybridizing a sample, does not reasonably provide enablement for a method wherein oligonucleotides do not detect SNPs. The specification does not enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

a) The claims are broad because they are drawn to a method for inferring a trait comprising contacting a sample with hybridizing oligonucleotides (oligos) wherein oligos can (but are not necessarily limited to) detect SNPs. The instant specification does not provide specific guidance to practice the invention for oligonucleotides that do not necessarily detect SNPs

b) The invention is drawn to a method of inferring or estimating a trait.

c, e) The prior art also shows that a sample is contacted with oligonucleotides that specifically detect SNPs and that SNPs information is used for identifying ancestral proportions. *See* Parra, *Am. J. Physical Antropol.*, 114-118 (2001) and McKeigue, *Ann. Hum. Genet.*, 64:171-186 (2000).

d) The skill of those in the art of molecular biology and bioinformatics is high.

f) The specification does not provide specific guidance to practice the invention because it does not disclose how to make or use the invention wherein oligos do not actually detect SNPs (line 5 of claim 1).

g) The specification provides working examples wherein a panel of oligonucleotides hybridizes to a sample DNA. The instant specification does not teach detecting the nucleotide occurrences of the AIMs without determining SNPs.

h) In order to practice the claimed invention, one skilled in the art must guess which parameters of a contacting step to use for the identifying a population structure if oligonucleotides do not necessarily detect SNPs. This constitutes undue experimentation.

Due to the undue experimentation required to obtain the goal of the invention, the lack of directions presented in the specification, the complex nature of the invention, and the state of the prior art, the specification fails to teach one skilled in the art how to use the claimed method for one individual at a time.

Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a method for inferring a trait comprising steps of contacting a sample with hybridizing oligonucleotides and identifying a population structure that correlates with AIMs in the test individual and the trait. The claim recites in step (a) "wherein said contacting is performed under conditions suitable for detecting ... AIMs of the test individual by the hybridizing oligonucleotides." It is not clear whether the method comprises actual, positive steps of hybridizing and detecting AIMs. It is also unclear whether contacting a sample with oligonucleotides actually "detects" the nucleotide occurrence of the AIMs. As the intended limitation is not clear, claims 1, 3-5, 7-9, 24, and 29-30 are indefinite.

Claim 1 recites in the preamble "a method of inferring." However, the method does not comprise an active, positive step of "inferring a trait." The proviso after step (b) recites "thereby inferring the trait." Thus, it is not clear whether "thereby inferring" is intended to be an active, positive step of inferring a trait, and therefore the relationship between the preamble and the method steps is unclear. As the intended limitation is not clear, claims 1, 3-5, 7-9, 24, and 29-30 are indefinite.

Claim 1 recites a method of inferring a trait. The method further recites "a population structure correlated with the trait" (line 7). Claim 1 also recites in line 13 "a trait" and in line 14 "the trait." It is not clear whether a population structure recited in line 13 correlates with the same or a different trait then the trait recited in lines 1 and 7. It is also unclear whether "the trait of the individual" recited in line 14 is the trait recited in lines 1 and 7 or the trait recited in line 13 (if different). As the intended limitation is not clear, claims 1, 3-5, 7-9, 24, and 29-30 are indefinite.

Claim 1 recites in line 5 "wherein the hybridizing nucleotides *can* detect ... SNPs." It is not clear whether oligonucleotides actually detect SNPs. As the intended limitation is not clear, claims 1, 3-5, 7-9, 24, and 29-30 are indefinite.

Claims 1, 24, 31, and 45 recite the limitation "identifying, with a predetermined level of confidence, a population (claims 1, 24, and 31) or sub-population (claim 45) structure. It is not clear whether " a predetermined level of confidence" is related to identifying, or a population structure, or a correlation of a population structure an the nucleotide occurrences of the AIMs, or a correlation of the population structure and a trait. As the intended limitation is not clear, claims 1, 3-5, 7-9, 24, 29-32, 38-45, and 47-58 are indefinite.

Claim 31 recites a method of estimating a trait comprising steps of contacting a sample with hybridizing oligonucleotides and identifying a population structure that correlates with AIMs in the test individual and the trait. The claim recites in step (a) "wherein said contacting is performed under conditions suitable for detecting ... AIMs of the test individual by the hybridizing oligonucleotides." It is not clear whether the method comprises actual, positive steps of hybridizing and detecting AIMs. The preamble recites "a method of estimating." However, the method does not comprise an active, positive step of "estimating a trait." The proviso after step (b) recites "thereby estimating the trait." Thus, it is not clear whether "thereby estimating" is intended to be an active, positive step of estimating a trait, and therefore the relationship between the preamble and the method steps is unclear. As the intended limitation is not clear, claims 31-32, 38-45, and 48-58 are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-5, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKeigue, *Ann. Hum. Genet.*, 64:171-186 (2000), in view of Birren, NCBI submission, ID number AC007172, (5/01/1999); or NCBI submission, ID number AI619784 (3/07/2000); or NCBI submission, ID number AI300757 (2/01/1999); and further in view of Collins-Schramm, *Am. J. Hum. Genet.*, 70:737-750 (2/11/2002).

McKeigue discloses estimating admixture in African-American population. (abstract) McKeigue discloses ten ancestry markers (p. 174). McKeigue discloses contacting a sample with oligonucleotides that can detect polymorphism because McKeigue discloses detecting polymorphism by using PCR which necessarily comprises oligonucleotides (p. 174, left col.). McKeigue discloses genotyping SNP markers (p. 182). McKeigue discloses identifying a population structure that correlates with ancestry markers and with a trait (p. 174, left col. and p. 177-178) thereby inferring the trait of the individual (p. 178). McKeigue discloses identifying with a predetermined level of confidence (tables 1-2 and p. 173). Thus, McKeigue discloses steps similar to those of instant claim 1. McKeigue also discloses biogeographical ancestry (BGA) trait (p. 175), similar to that of instant claims 3 and 31.

McKeigue does not disclose using an AIM set forth in SEQ ID NO:70.

All NCBI submissions teach a polynucleotide SEQ ID NO:70.

Collins-Schramm discloses a large-scale screening of ethnic-difference human markers (abstract). Collins-Schramm discloses collecting samples from individuals having Mexican American, African American, Amerindian, and European ancestry, isolating DNA, and screening for ethnic-difference markers (p. 738-739). Collins-Schramm discloses a large list of identified ancestry markers located on different human chromosomes (table 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of McKeigue to use AIM of SEQ ID NO:70, such as taught by the NCBI submissions, where the motivation would have been to facilitate detection of ancestral proportions in human, as taught by Collins-Schramm, *see* p. 737-738, *Introduction.*

Claims 1, 3-5, 31, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parra, *Am. J. Physical Antropol.*, 114-118 (2001), in view of Birren, NCBI submission, ID number AC007172, (5/01/1999); or NCBI submission, ID number AI619784 (3/07/2000); or NCBI submission, ID number AI300757 (2/01/1999); and further in view of Collins-Schramm, *Am. J. Hum. Genet.*, 70:737-750 (2/11/2002).

Parra discloses a method for inferring ancestral proportions and admixture in African-Americals (abstract). Parra discloses ten ancestry markers (p. 20 and table 1). Parra discloses contacting a sample with oligonucleotides that can identify SNPs (PCR, p. 20, left col.). Parra discloses identifying a population structure that correlates with ancestry markers and with a trait (table 1, fig. 1, p. 22). Parra discloses identifying with a predetermined confidence interval (p. 21). Thus, Parra discloses steps similar to those of instant claim 1. Parra discloses BGA trait (fig. 1 and p. 25), similar to that of instant claims 3 and 31. Parra discloses calculating individual admixture proportions using a maximum likelihood method of Chakraborty (p. 20 and 21-22), similar to that of instant claim 39.

Parra does not disclose using an AIM set forth in SEQ ID NO:70.

All NCBI submissions teach a polynucleotide SEQ ID NO:70 (cDNA clones obtained from human chromosomes).

Collins-Schramm discloses a large-scale screening of ethnic-difference human markers (abstract). Collins-Schramm discloses collecting samples from individuals having Mexican American, African American, Amerindian, and European ancestry, isolating DNA, and screening for ethnic-difference markers (p. 738-739). Collins-Schramm discloses a large list of identified ancestry markers located on different human chromosomes (table 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Parra to use AIM of SEQ ID NO:70, such as taught by the NCBI submissions, where the motivation would have been to screed large variety of human chromosome fragments for ancestral markers and use the identified markers for determining ancestral proportions in human, as taught by Collins-Schramm, *see* p. 737-738, *Introduction.*

Claims 1, 3-5, 24, 30-31, 45, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorenson, US 2003/0172065, in view of Birren, NCBI submission, ID number AC007172, (5/01/1999); or NCBI submission, ID number AI619784 (3/07/2000); or NCBI submission, ID number AI300757 (2/01/1999); and further in view of Collins-Schramm, *Am. J. Hum. Genet.*, 70:737-750 (2/11/2002).

Sorenson discloses a method of determining ancestral proportions and admixture in the diverse population (fig. 4). Sorenson discloses contacting a sample with oligonucleotides (PCR; fig. 4 and [0039]) wherein oligos can detect SNPs ([0042] and table 1 showing a panel of at least ten ancestry markers and oligonucleotides for the identification of SNPs). Sorenson discloses identifying a population structure (fig. 4 and [0032], [0046]-[0047]) that correlates with markers and a trait. Sorenson discloses identifying a population structure with a predetermined confidence interval and statistical probability [[0048], [0061]. Thus, Sorenson discloses steps similar to those of instant claim 1. Sorenson also discloses a trait of BGA [0012], [0032], similar to that of claims 3 and 31. Sorenson discloses identifying a subpopulation structure (members of one group) [0047], similar to that of instant claims 24 and 45. Sorenson teaches that thousands of known genetic markers and millions of characterized SNPs may be analyzed [0042], similar to

that of instant claim 30. Sorenson discloses comparing of the nucleotide occurrence of markers with known proportional ancestry, and specifically the occurrence that is contained in a database ([0017], [0020], [0047] and fig. 4, claims 1, 6-7, 9, 13-18), similar to that of instant claims 50-52. Sorenson discloses a large list of human ancestral markers (tables 1-4).

Sorenson does not disclose using an AIM set forth in SEQ ID NO:70.

All NCBI submissions teach a polynucleotide SEQ ID NO:70.

Collins-Schramm discloses a large-scale screening of ethnic-difference human markers (abstract). Collins-Schramm discloses collecting samples from individuals having Mexican American, African American, Amerindian, and European ancestry, isolating DNA, and screening for ethnic-difference markers (p. 738-739). Collins-Schramm discloses a large list of identified ancestry markers located on different human chromosomes (table 1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Sorenson to use AIM of SEQ ID NO:70, such as taught by the NCBI submissions, where the motivation would have been to facilitate detection of ancestral proportions in human, as taught by Collins-Schramm, *see* p. 737-738, *Introduction.*

Claims 7-8, 32, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sorenson, US 2003/0172065, in view of Birren, NCBI submission, ID number AC007172, (5/01/1999); or NCBI submission, ID number AI619784 (3/07/2000); or NCBI submission, ID number AI300757 (2/01/1999); in view of Collins-Schramm, *Am. J. Hum. Genet.*, 70:737-750 (2/11/2002), as applied to claims 1, 3-5, 24, 30-31, 45, and 50-52, and further in view of Hanis, *Am. J. Physical Anthropol.*, 70:433-441 (1986).

Sorenson, Collins-Schramm, and the NCBI submissions make obvious the method of claim 1, as set forth above. Sorenson also teaches a panel of ancestral markers (tables 1-3).

Sorenson, Collins-Schramm, and the NCBI submissions do not disclose sub-Saharan African, Native American, Indo-European, or East Asian ancestral groups and a marker that is not linked to a gene linked to a trait.

Hanis discloses estimating individual admixture based on ancestral markers wherein a marker does not detect a disease (a trait, *i.e.*, diabetes and gallbladder), but detects ancestry (ancestral marker). Hanis conducts his research for Native American, African, Mexican-American, and European ancestral groups.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Sorenson, Collins-Schramm, and the NCBI submissions to use AIM that are not linked to a gene linked to a trait for a population having sub-Saharan African, Native American, Indo-European, or East Asian ancestry, such as taught by Hanis, where the motivation would have been to estimate the relationship of individual admixture to diabetes and gallbladder disease status, as taught by Hanis, p. 433 and 437.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorenson, US 2003/0172065, in view of Birren, NCBI submission, ID number AC007172, (5/01/1999); or NCBI submission, ID number AI619784 (3/07/2000); or NCBI submission, ID number AI300757 (2/01/1999); in view of Collins-Schramm, *Am. J. Hum. Genet.*, 70:737-750 (2/11/2002), as applied to claims 1, 3-5, 24, 30-31, 45, and 50-52, and further in view of Kanetsky, *Am. J. Hum. Genet.*, 70:770-775 (2/6/2002).

Sorenson, Collins-Schramm, and the NCBI submissions make obvious the method of claim 1, as set forth above. Collins-Schramm discloses ancestral markers for mapping by admixture linkage disequilibrium for the population comprising African (Zimbabwe, *i.e.*, sub-Saharan Africa), Amerindian, European, and Mexican ancestry (abstract).

Sorenson, Collins-Schramm, and the NCBI submissions do not specifically teach BGA from Asian ancestral groups.

Kanetsky discloses white, African, Spanish, Hispanic, Native Indian, Aboriginal, and Asian ancestry (p. 772).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Sorenson, Collins-Schramm, and the NCBI submissions to use BGA comprising at least three groups from Asian ancestral groups, such as taught by Kanetsky, where the motivation would have been to determine ancestral proportions of different groups of Americans for mapping complex genetic diseases, as taught by Collins-Schramm, p. 737.

Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorenson, US 2003/0172065, in view of Birren, NCBI submission, ID number AC007172, (5/01/1999); or NCBI submission, ID number AI619784 (3/07/2000); or NCBI submission, ID number AI300757 (2/01/1999); in view of Collins-Schramm, *Am. J. Hum. Genet.*, 70:737-750 (2/11/2002), as applied to claims 1, 3-5, 24, 30-31, 45, and 50-52, and further in view of Akey, *BioTechnique*, 30(2):358-367 (2001).

Sorenson, Collins-Schramm, and the NCBI submissions make obvious the method of claim 1, as set forth above.

Although Sorenson teaches that thousands of known genetic markers and millions of characterized SNPs may be analyzed, Sorenson, Collins-Schramm, and the NCBI submissions do not specifically teach high-throughput methods.

Akey discloses a high-throughput genotyping technique (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Sorenson, Collins-Schramm, and the NCBI submissions to use high-throughput methods, such as taught by Akey, where the motivation would have been to improve genetic mapping, as taught by Akey, p. 358.

Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Parra, *Am. J. Physical Antropol.*, 114-118 (2001), in view of Birren, NCBI submission, ID number AC007172, (5/01/1999); or NCBI submission, ID number AI619784 (3/07/2000); or NCBI submissions ID number AI300757 (2/01/1999); in view of Collins-Schramm, *Am. J. Hum. Genet.*, 70:737-750 (2/11/2002), as applied to claims 1, 3, 31, and 39, and further in view of Pritchard, *Theoretical Population Biology*, 60:227-237 (2001).

Parra, Collins-Schramm, and the NCBI submissions make obvious the method of claims 1, 3, 31, and 39, as set forth above.

Parra, F Collins-Schramm, and the NCBI do not disclose a multiple way comparison and a graphical representation.

Pritchard discloses statistical methods for determining the population structure and admixture. Pritchard discloses generating graphical representation of the comparison of three ancestral groups wherein ancestral groups are represented by a vertex of a triangle, and wherein the maximum likelihood of proportional affiliation for an individual comprises a point within the triangle (fig. 1 and p. 232-233). Pritchard discloses six two-way analysis (1-2; 2-1; 2-3; 3-2; 1-3; and 3-1) (fig. 1). Pritchard discloses three three-way analyses (1-2-3; 2-3-1; and 3-2-1).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Parra, Collins-Schramm, and the NCBI to conduct multiple way analysis of the likelihood and graphically represent the result, such as taught by Pritchard, where the motivation would have been to avoid an influence of a high rate association of markers and time consuming and expensive assembling of family-based samples, as taught by Pritchard, *see* Introduction, p. 227-228.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sorenson, US 2003/0172065, in view of Birren, NCBI submission, ID number AC007172, (5/01/1999); or NCBI submission, ID number AI619784 (3/07/2000); or NCBI submission, ID number AI300757 (2/01/1999); in view of Collins-Schramm, *Am. J. Hum. Genet.*, 70:737-750 (2/11/2002), as applied to claims 1, 3-5, 24, 30-31, 45, and 50-52, and further in view of Pritchard, Pritchard, *Genetics*, 155:945-959 (2000).

Sorenson, Collins-Schramm, and the NCBI submissions make the method of claim 31 obvious, as set forth above.

Sorenson, Collins-Schramm, and the NCBI submissions do not specifically disclose generating an ancestral map.

Pritchard discloses statistical methods for determining the population structure and admixture (abstract). Pritchard discloses an ancestral map and the correspondence to the proportional ancestry (fig. 3 and fig. 6).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Sorenson, Collins-Schramm, and the NCBI submissions to generate an ancestral map, such as taught by Pritchard, where the motivation would have been to test for clustering for samples representing distinct populations, as taught by Pritchard, p. 951.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller
Examiner
Art Unit 1631

MM

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
2/6/06